

**Application Note**

**Calprotectin Turbilatex, AU680, Beckman Coulter**  
(AN-Cp-AU680.EN rev 2019.05.27)

For *in vitro* diagnostic device  
ENGLISH



## General Information

### Intended use:

Calprotectin Turbilatex is a latex turbidimetric assay for the quantitative detection of calprotectin (hCp) in human stool samples.

This assay is simple and widely applicable. Test results aid in a presumptive diagnosis of IBD patient with inflammation and from irritable bowel syndrome (IBS).

For professional *in vitro* diagnostic use only.

Calprotectin Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions in order to assure performance characteristics as describes in the instructions for use. This instruction has been validated by CerTest BIOTEC S.L. Laboratories.

Additionally, please read the "Instructions for use" for instructions on operating and programming user defined test

### Reagents:

#### Materials provided by CerTest BIOTEC S.L.:

Reagents	Quantity	Cat. reference
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x27 mL. R2: 1 vial, 1x8 mL.	TL-022CP01 TL-022CP02
Auxiliary Reagents	Quantity	Cat. reference
Calibration kit	Calibrator: 6 vials, 6x1mL.	TL-022CP70, TL-022CP71, TL-022CP72, TL-022CP73, TL-022CP74, TL-022CP75
Controls kit	Control C1, 2 vials, 2x1mL/vial. Control C2, 2 vials, 2x1mL/vial.	TL-022CP08 TL-022CP09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022CP03E
Sample dilutions vials	1x2 mL/vial 1x2 mL/vial	MST-0006MC MST-0008C

### Preparation of reagents:

R1 and R2 are ready to use.

Calibrators are ready to use.

Controls are ready to use

### Storage and stability

Kit components must be stored at temperature indicated on the label. Do not freeze.

Reagents are stable up to the expiration date printed on the label, always considering that reagent containers must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at temperature indicated on the label of each reagent.

### Specimen:

Collect enough quantity of human stool samples. These samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C) for 7 days prior to testing. For longer storage, maximum 6 months, the specimen must be kept frozen at -20°C. In this case, the sample will be totally thawed, and brought to room temperature (15-30°C) before testing. Freezing and thawing cycles are not recommended. Homogenise stool samples as thoroughly as possible prior to preparation.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8°C) prior to testing.

Use Calprotectin Turbilatex stool collection tubes for sample collections described the instructions for use.

## Assay procedure

### Application parameter set up:

Specific analyzers settings for Calprotectin Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the AU680 (Beckman Coulter) analyzer manual and instructions for use provided with the kit.

### Loading of reagents:

Load reagents according to the AU680 (Beckman Coulter) analyzer manual.

### Calibration curve establishment:

A 6 points calibration curve can be established in AU680 (Beckman Coulter) analyzer. For instructions consult analyzer manual.

### Calibration stability:

Calibrate the system at least once a month is extremely recommended. Recalibrate the system when reagent lot is change or when the controls are out of the assigned range given in the control label and CoA.

### QC controls:

Calprotectin Turbilatex controls C1 and C2 must be assayed each day before running patient fecal sample extract to validate the calibration curve. The controls have assigned value ranges indicated on the label and certificate of analysis supplied. The control measurements must be within the indicated value range to obtain valid results for patient fecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

### Results:

The results are evaluated automatically by the analyzer and presented in µg hCp/g of stool.

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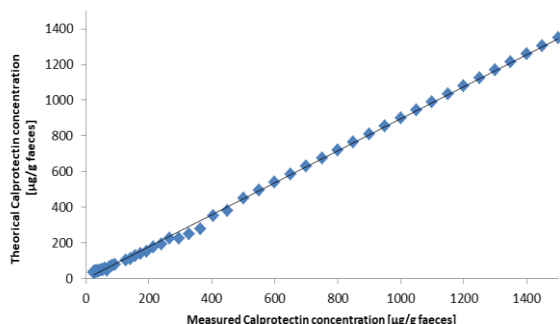


## Performance characteristics

The following results have been obtained during the validation of Calprotectin Turbilatex on the AU680 (Beckman Coulter) analyzer.

### Linearity:

Calprotectin Turbilatex on AU680 (Beckman Coulter) analyzer using calibrator kit is linear in the calibration range of 0-1500  $\mu\text{g hCp/g}$  of stool.



### Measuring range:

Calprotectin Turbilatex assay measuring range is 20-8000  $\mu\text{g hCp/g}$  of stool on the AU680 (Beckman Coulter) analyzer. Samples higher concentrated than 1500  $\mu\text{g hCp/g}$  of stool must be diluted for proper quantification by the user, using additional sample buffer.

### Prozone effect

Using the reported parameters, no hook effect was observed up to 8000  $\mu\text{g hCp/g}$  of stool. Samples with calprotectin concentration of 8000  $\mu\text{g hCp/g}$  of stool give a typical positive result  $>1500 \mu\text{g hCp/g}$ .

### Detection limit

**Limit of detection (LOD): 15  $\mu\text{g hCp/g}$  of stool.** The lower limit of detection of Calprotectin Turbilatex was determined on 20 samples and 2 sample replicates as the mean value + 2xSD.

**Limit of quantification (LOQ): 20  $\mu\text{g hCp/g}$  of stool.** The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is  $< 20\%$  as CV% on the AU680 (Beckman Coulter) analyzer.

## Precision

Calprotectin Turbilatex was tested with three different controls levels.

	Low (50 $\mu\text{g/g}$ )	Medium (100 $\mu\text{g/g}$ )	High (750 $\mu\text{g/g}$ )
N	20	20	20
Mean ( $\mu\text{g/g}$ )	47,5	101,1	751,1
SD ( $\mu\text{g/g}$ )	1,2	2,5	17,4
CV (%)	3%	2%	2%

## Method comparison

Results obtained with Calprotectin Turbilatex on AU680 (Beckman Coulter) analyzer were compared with a commercial immunoassay (Calprest<sup>®</sup>, Eurospital).

	Sensitivity	Specificity
Calprotectin Turbilatex vs Calprest <sup>®</sup>	94%	$>99\%$

## Shipping damage

Please notify your distributor, if this product was received damaged.

## Symbols key

	For <i>in vitro</i> diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
	Catalogue number		Lot number
	Use by		Manufacturer
	Contains sufficient for $<n>$ test		Sample diluent
	Keep out of the sunlight		

## Manufacturer

### CERTEST BIOTEC

Pol. Industrial Río Gállego II, Calle J, Nº 1, 50840,  
San Mateo de Gállego, Zaragoza (SPAIN)  
www.certest.es

## NOTES

Please refer to the instructions for use for the detailed information about the test on the following:

**Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.**

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ENGLISH**AU680, Beckman Coulter / Application parameters**

<b>ASSAY PARAMETERS</b>	
Std. No	6
R1	125 µL
Sample	2.5 µL
R2	15 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	450 nm
Secondary wavelength	800 nm
Direction	Increase
Reagent blank lecture	11 cycle
Final lecture	27 cycle
Reaction time	10 min
Linear range	0-1500 µg/g
<b>CALIBRATION</b>	
Calibration Method	Linear
Calibration set	6 calibrators
Blank	Calibrator 1 (0 µg/g)
Calibrator 1	Calibrator 2 (50 µg/g)
Calibrator 2	Calibrator 3 (100 µg/g)
Calibrator 3	Calibrator 4 (250 µg/g)
Calibrator 4	Calibrator 5 (750 µg/g)
Calibrator 5	Calibrator 6 (1500µg/g)
<b>STEPS</b>	
Addition R1	
Addition Sample	
Incubation	5 min
Addition R2	
Blank Lecture	
Incubation	5 min
Final lecture	



Parameters		Specific Test Parameters	
General		LIT	ISE
HbA1c		Calculated Tests	
Range			
Test Name	117.Cal	Type	Serum
Operation	Yes		
Sample Volume	2.5 uL	Dilution	0 uL
Pre-Dilution Rate	1	OD Limit	Min.OD: -2.0000, Max.OD: 3.0000
Reagent Volume R1(R1-1)	125 uL	Dilution	0 uL
Reagent OD Limit		First	Low: -2.0000, High: 3.0000
Reagent OD Limit		Last	Low: -2.0000, High: 3.0000
Reagent Volume R2(R2-1)	15 uL	Dilution	0 uL
Dynamic Range		Low	-9999999
Dynamic Range		High	9999999
Common Reagent Type	None	Name	
Wave Length Pri.	450 nm	Sec.	800 nm
Correlation Factor	A: 1, B: 0		
Method	FIXED	Factor for Maker	A: 1, B: 0
Reaction Slope	+	Onboard Stability Period	Day: , Hour:
Measuring Point-1 First	11	Last	27
Measuring Point-2 First		Last	
Linearity Limit	%		
Lag Time Check			
Edit		List Display	Print

Calibration		Calibration Monitor																						
Status	RB History	RB Detail	Calibration History																					
Calibration Detail																								
Test Name	117.Cal	Type	Serum																					
Date/Time	9/13/2018 12:17 PM	Passed																						
Reagent Lot No.		Bottle No.																						
R1(R1-1)		R2(R2-1)																						
Cal Expiration Date																								
Reagent Blank	9/13/2018 09:06 AM																							
Cal Type	6AB																							
Measure Type	Rack																							
Formula	Polygonal																							
Factor																								
A0	8.1301E003																							
B0	2.0000E-004																							
A1	8.1301E003																							
		<table border="1"> <thead> <tr> <th>Cal No.</th> <th>CONC</th> <th>OD</th> </tr> </thead> <tbody> <tr><td>1</td><td>1</td><td>0</td></tr> <tr><td>2</td><td>2</td><td>50</td></tr> <tr><td>3</td><td>3</td><td>100</td></tr> <tr><td>4</td><td>4</td><td>250</td></tr> <tr><td>5</td><td>5</td><td>750</td></tr> <tr><td>6</td><td>6</td><td>1500</td></tr> </tbody> </table>	Cal No.	CONC	OD	1	1	0	2	2	50	3	3	100	4	4	250	5	5	750	6	6	1500	
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